

REMARKS**Claim Amendments**

Claims 7-10 are canceled. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the invention in the canceled claims. Applicants do not hereby abandon or waive any rights in the inventions in the canceled claims.

Claims 2-6, 12, 14-20, 22-24, 26, 27, 29-34, 36-38 and 45 are amended.

Claims 2-6, 12, 14-18, 20, 23, 24, 26, 27, 29-34 and 36-38 are amended to properly begin the claim with the article "The".

Claims 4, 12, 18, 20, 23, 27, 29 and 38 are amended to delete elements from the Markush group, namely an antibody having an epitopic specificity which is the same as or similar to that of 1G1, 2B10 and 10E4. Support for this amendment is found in the specification, for example, at page 4, lines 5-12.

Claims 12, 18, 27 and 38 are further amended to recite combinations of the claimed antibodies and antigen-binding fragments thereof. Support for this amendment is found in the specification, for example, at page 13, line 26 through page 14, line 11.

Claim 19 is amended to correct use of an antecedent term error.

Claim 23 is further amended to correct obvious typographical errors.

Claim 45 is amended to present the claim in independent form.

Claims 46-49 are added. Support for these new claims is found in the specification, for example, at page 3, line 28.

No new matter is added.

Objection to Claims 9, 10 and 45 Under 37 C.F.R. §1.75(c)

Claims 9, 10 and 45 are rejected to under 37 C.F.R. §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 9 and 10 are canceled, therefore the objection to these claims is moot.

Claim 45, as amended, is now an independent claim, thereby obviating the objection.

Reconsideration and withdrawal of the objection are respectfully requested.

Rejection of Claims 7-10 Under 35 U.S.C. §101

Claims 7-10 are rejected under 35 U.S.C. §101 as a double patenting rejection as claiming the same invention as that of Claims 2 to 5 of U.S. Patent No. 6,488,930.

Applicants have canceled Claims 7-10, thereby obviating the rejection.

Reconsideration and withdrawal of the rejection are respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 1-12 and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 to 64 of U.S. Patent No. 6,488,930.

As indicated above, Claims 7-10 are canceled. With respect to Claims 1-6, 11, 12 and 39-41, Applicants will file a Terminal Disclaimer to overcome the obviousness-type double patenting rejection, as appropriate, upon notice of otherwise allowable subject matter in the present application. This will permit Applicants to consider the rejection in view of the claims as ultimately indicated to be allowable since it is possible that the claims may change during the course of prosecution.

Rejection of Claims 4, 7-10, 12, 18, 20, 21, 23, 27, 29, 38, 44 and 45 Under 35 U.S.C. §112,First Paragraph

Claims 4, 7-10, 12, 18, 20, 21, 23, 27, 29, 38, 44 and 45 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner requests a declaration regarding the biological material 1G1 and 2B10 (Applicants assume this also applies to biological material 10E4).

Filed concurrently herewith is Applicants' agent's Statement Under 37 C.F.R. §1.806 and §1.808 with Exhibits A and B, which are copies of the American Type Culture Collection (ATCC) deposit receipts for said biological deposits.

Therefore, pursuant to 37 C.F.R. §1.809(b)(1), Applicants submit that, with regard to the biological deposits described in the specification, for example, at page 13, lines 12-25, the claims are enabled.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 4, 12, 18, 20, 21, 23, 27, 29 and 38 Under 35 U.S.C. §112, First Paragraph

Claims 4, 12, 18, 20, 21, 23, 27, 29 and 38 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Specifically, the Examiner asserts that the claims encompass an antibody which has an epitopic specificity which is the same as or similar to that of 1G1, 2B10 or 10E4, and “[b]ecause the instant specification does not disclose the epitope to which 1G1 or 2B10 binds, an artisan cannot produce an antibody with the same binding specificity” (Office Action, page 5, first full paragraph).

Applicants respectfully disagree. However, to expedite prosecution, Applicants have amended Claims 4, 12, 18, 20, 23, 27, 29 and 38, which, as amended, do not recite an antibody having an epitopic specificity which is the same as or similar to 1G1, 2B10 or 10E4. Thus, Claims 4, 12, 18, 20, 23, 27, 29, 38, as amended, and Claim 21, which depends from Claim 20, are fully enabled. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 4, 12, 18, 20, 21, 23, 27, 29 and 38 Under 35 U.S.C. §112, Second Paragraph

Claims 4, 12, 18, 20, 21, 23, 27, 29 and 38 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserts that the claims are vague and indefinite in the recitation of the term “similar to”.

Applicants respectfully disagree. However, as noted above, Claims 4, 12, 18, 20, 23, 27, 29 and 38, as amended, and Claim 21 which depends from Claim 20, do not recite the term “similar to,” thereby obviating the rejection.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-3, 5, 6, 11, 13-17, 19, 22, 24-26, 28, 30-37 and 39-43 Under 35 U.S.C. §103(a)

Claims 1-3, 5, 6, 11, 13-17, 19, 22, 24-26, 28, 30-37 and 39-43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Power *et al.*, (*J. Biol. Chem.*, 270(33):19495-19500 (1995)) in view of Chuntharapai *et al.*, (*Methods in Enzymology*, 288:15-27 (1997)).

Specifically, the Examiner asserts that:

[b]ecause Figure 2 of the Power *et al.* publication taught the close relationship of the [CCR4] receptor described there to Human interleukin receptor A and Human interleukin receptor B and the methods of Chuntharapai *et al.* were exemplified by the production of blocking monoclonal antibodies to each of these two IL-8 receptors an artisan had more than a reasonable expectation that the methods of Chuntharapai *et al.* would be readily applicable to the production of blocking monoclonal antibodies to the chemokine receptor that was described by Power *et al.* prior to the making of the instant invention. (Office Action, page 7).

Applicants respectfully disagree. Power *et al.* teach that K5-5 (*i.e.*, CCR4) has only 42% amino acid identity and 41% amino acid identity to IL-8 receptors A and B, respectively (page 19497, column 2). Furthermore, Power *et al.* teach that the:

greatest divergence occurs in the N-terminal extracellular domain, **which has been shown to control ligand binding specificity** in the IL-8 receptors (page 19497, column 2; emphasis added).

Examination of sequence alignment of Power *et al.* in Figure 2 reveals that the N-terminal extracellular domain of CCR4 (stated by Power *et al.* to control ligand binding specificity) has only 2 identical amino acids and 3 identical amino acids out of 39 amino acids to IL-8 receptors A and B, respectively, *i.e.*, only 5% and 8% amino acid identity.

Thus, Power *et al.* does **not** teach a “close relationship” of CCR4 to IL-8 receptors A and B at the region described by Power *et al.* to “control ligand binding specificity”. Instead, Power

et al. teach that **CCR4 shares no significant relationship** at the region where the IL-8 receptors “control ligand binding specificity”. Thus, the teachings of Chuntharapai *et al.*, even if properly combined with Power *et al.*, would not provide a person of skill in the art a reasonable expectation of success since Chuntharapai *et al.* only disclose the production of antibodies to the IL-8 receptor A and IL-8 receptor B. As already discussed, IL-8 receptor A shares only 5% amino acid identity with CCR4 at the region characterized by Power *et al.* to control ligand binding specificity. Thus, the person of skill in the art would have no motivation to combine the teachings of Power *et al.* with Chuntharapai *et al.*, and furthermore, even if improperly combined, there is no expectation of success since there is no significant relationship between CCR4 and the IL-8 receptor A at the region described by Power *et al.* to control ligand binding specificity.

Therefore, since the combination of Power *et al.* and Chuntharapai *et al.* does not teach or suggest an antibody or antigen-binding fragment thereof which binds to a mammalian CCR4, or portion of said receptor, and which inhibits binding of a ligand to the receptor, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

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Dated: *September 12, 2005*

September 12, 2005



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Lijun Wu, Nancy Ruffing and David P. Andrew

Application No.: 10/055,789

Group: 1646

Filed: January 18, 2002

Examiner: John D. Ulm

For: ANTI-CCR4 ANTIBODIES AND METHODS OF USE THEREFOR

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>9-12-05</u>	<u>Dawn M Myers</u>
Date	Signature
<u>Dawn M Myers</u>	
Typed or printed name of person signing certificate	

STATEMENT UNDER 37 C.F.R. §1.806 and §1.808

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. §1.806 and §1.808, the undersigned attorney states as follows:

1. The above-referenced application contains reference to three biological deposits deposited under the Budapest Treaty at the American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209. Murine hybridomas 1G1 (LS141-1G1-65-15-1) and 2B10 (LS185-2B10-4-1) were deposited on January 6, 1999, and assigned ATCC Accession Numbers HB-12624 and HB-12625, respectively. Murine hybridoma 10E4 (LS257-10E4.1.1) was deposited on January 14, 2000, and assigned ATCC Accession Number PTA-1203. A copy of the ATCC Deposit Receipt for deposits ATCC Accession Numbers HB-12624

and HB-12625 is attached as Exhibit A. A copy of the ATCC Deposit Receipt for deposit ATCC Accession Number PTA-1203 is attached as Exhibit B.

2. Deposits HB-12624, HB-12625 and PTA-1203 will be maintained in a public depository for the enforceable life of the patent which issues from the above-referenced application, a term of at least thirty years from the date of deposit or at least five years after the most recent request for the furnishing of a sample of the deposit is received by the depository, whichever is longer.
3. In accordance with 37 C.F.R. §1.808(a)(1), access to deposits HB-12624, HB-12625 and PTA-1203 will be available during the pendency of the above-referenced application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. §1.14 and 35 U.S.C. §122.
4. In accordance with 37 C.F.R. §1.808(a)(2), and except as permitted by 37 C.F.R. §1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the above-referenced application.

Respectfully submitted,

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Dated: September 12, 2005

ATCC

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

LeukoSite, Inc.
Attn: Lijun Wu
215 First Street
Cambridge, MA 02142

Deposited on Behalf of: LeukoSite, Inc.

Identification Reference by Depositor:

ATCC Designation

Murine hybridoma 1G1 (LS141-1G1-65-15-1)
Murine hybridoma 2B10 (LS185-2B10-4-1)

HB-12624
HB-12625

The deposits were accompanied by: ___ a scientific description ___ a proposed taxonomic description indicated above. The deposits were received January 6, 1999 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will not inform you of requests for the strains.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

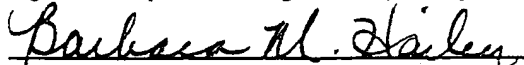
If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested January 18, 1999. On that date, the cultures were viable.

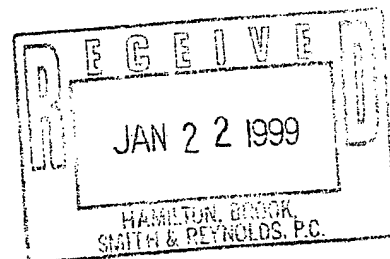
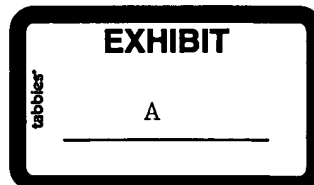
International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:


Barbara M. Hailey, Administrator, Patent Depository

Date: January 18, 1999

cc: David E. Brook, Esq. (Ref. Docket LKS98-15)



ATCC

FEB - 7 2000

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

LeukoSite, Inc.
Attn: David Andrew, Ph.D.
215 First Street
Cambridge, MA 02142

Deposited on Behalf of: LeukoSite, Inc.

Identification Reference by Depositor:

Patent Deposit Designation

Murine hybridoma 10E4 (also known as LS257-10E4.1.1)

PTA-1203

The deposit was accompanied by: a scientific description a proposed taxonomic description indicated above.

The deposit was received January 14, 2000 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: X We will not inform you of requests for the strain.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested February 4, 2000. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: February 4, 2000

cc: Helen E. Wendler, Esq. (Ref. Docket 1855.1063-002 PCT and 1855.1063-003)

EXHIBIT

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